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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,907	11/20/2006	Graham Mcintyre	15131.0003	6019

27890 7590 02/06/2008

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
02/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/577,907	MCINTYRE ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *18January2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *12,13,22 and 23*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 19 September 2007, is acknowledged. Claims 12 and 13 have been amended. Claims 15-21 have been cancelled.

2. Claims 12, 13, 22, and 23 are pending and under consideration.

Rejections Moot or Withdrawn

3. The rejection of claims 15-21 under 35 U.S.C. 112, first paragraph, scope of enablement for the method for treating or preventing any/all autoimmune diseases or disorders, is moot in light of the cancelation of the claims.

Rejections Maintained

4. The rejection of claims 12, 13, 22, and 23 under 35 U.S.C. 112, first paragraph, scope of enablement for the method for treating or preventing any/all autoimmune diseases or disorders, is maintained.

Applicants argue that the amendment of the claims to now recite "wherein the autoimmune disease or autoimmune disorder involves inflammation of the intima of a blood vessel and is a vascular disorder selected from the group consisting of atheroma formation, myointimal hyperplasia, inflammatory and autoimmune thickening of the intema and/or muscular layer of blood vessels and mycoarditis" obviates the rejection. Coupled with the various examples, e.g., Example 10, 11, 12, in the specification the scope of the instant claims is well supported.

The examiner has considered applicants' arguments, but does not find them persuasive.

Claim 12 is drawn to a method for treating or preventing an autoimmune disease or an autoimmune disorder. These disorders "involve" inflammation of the intima of a blood vessel.

The vascular disorder is selected from the group consisting of: 1) atheroma formation, 2) myointimal hyperplasis, and, 3) inflamatory and autoimmune thickening of the intima and/or muscular layer of blood vessels and myocarditis.

Example 10 is a rat model involving balloon angioplasty. On days 0 and 21, rats were injected with control and experimental compositions. On day 56, the rats underwent balloon angioplasty of the carotids. On day 70, all rats were euthanized and organs collected for study. While the experimental compositions appear to have reduced inflammation, they did not prevent the inflammation, as is claimed.

Example 11 is a rat model of myocarditis following infection by *T. cruzi*. On days 1 and 14, rats were injectd with control and experimental compositions. On day 21, the rats were subcutaneously infected with live *T. cruzi*. After blood assessment 7 and 14 days after infection, a second injection with *T. cruzi* occurred on day 42. While the experimental composition appear to have reduced parasitemia and altered CD4 positive cells in the myocardium, the composition did not prevent the inflammation, as is claimed, nor at the time of filing of the application, reduce inflammation utilizing all of the bacteria, commensurate with the scope of the claime. Page 54, lines 13-17, state "The heart muscle of further test subjects will be analysed 3 months after infection with T.cruzi for assessment of chronic myocarditis. Preliminary investigations have shown that Mycobacterium vaccae has a beneficial effect in reducing chronic myocarditis and it is expected from the above data that some of the test organisms will have beneficial effects in the prevention of chronic myocarditis."

Example 12 is merely a protocol for future experimentation and does not provide any evidence to support the instant claim, except for one statement, page 65, lines 9-10, that "Preliminary investigations suggest that T. inchonensis reduces post-coronary- 10 angioplasty

myointimal hyperplasia (MIH). Thus, the evidence from Example 12 does not support the broad scope of the claim, i.e., prevention or treatment of autoimmune disease or disorder using any of 6 genera of bacteria.

Claim 13 is a method for immunizing a subject against an autoimmune disease or autoimmune disorder comprising administration of the same compositions as in claim 12. The discussion of examples 10-12, *supra*, show that the specification is also lacking in support for immunization against the claimed disorders/diseases.

Claims 22 and 23 depend from claims 12 and 13 and therefore also lack sufficient support for the scope of these claims for identical reasoning as applied to claims 12 and 13.

Conclusion

5. Claims 12, 13, 22, and 23 remain rejected.

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

January 23, 2008